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Attorney General's Office Plays Leading Role in Historic Consumer Protection Action
AstraZeneca will pay \$68.5 million to 38 states; Delaware to receive \$1.4 million

WILMINGTON – Delaware and 37 other states reached a record \$68.5 million settlement with AstraZeneca Pharmaceuticals LP over allegations the company improperly marketed the drug Seroquel, the Attorney General's office announced today.

The Attorney General's Consumer Protection helped lead the investigation that resulted in the agreement, which is the largest consumer protection settlement with a pharmaceutical company in U.S. history. The First State's share of the settlement -- \$1.4 million -- will go to the Attorney General's Consumer Protection Fund.

"The health and safety of patients was our prime concern in this investigation," stated Timothy Mullaney, Sr, Director of the Attorney General's Fraud and Consumer Protection Division. "This agreement ensures that Seroquel will be promoted only for uses approved by the FDA and that consumers benefit from more transparent and accurate information. We were proud to have a leading role in this investigation and we will continue to act aggressively to protect Delaware consumers and enforce fair business practices."

The states allege that AstraZeneca engaged in unfair and deceptive practices when it marketed Seroquel for unapproved or off-label uses, failed to adequately disclose the drug's potential side effects to health care providers, and withheld negative information contained in scientific studies concerning the safety and efficacy of Seroquel.

Following a 3-year investigation, AstraZeneca agreed not to promote Seroquel for "off-label" uses which are not approved by the U.S. Food and Drug Administration. In addition to the \$68.5 million payment, settlement includes prohibitions and requirements that address concerns identified in the investigation. Specifically, the agreement requires AstraZeneca to:

- Publicly post its payments to physicians on a website;
- Have policies in place to ensure that financial incentives are not given to marketing and sales personnel for off-label marketing;
- Have policies in place to ensure that AstraZeneca sales personnel do not promote to health care providers who are unlikely to prescribe Seroquel for an FDA-approved use; and
- Cite to Seroquel's FDA-approved indications when referencing selected symptoms, rather than promoting Seroquel by highlighting symptoms only.

Although a physician is allowed to prescribe drugs for off-label uses, law prohibits pharmaceutical manufacturers from marketing their products for off-label uses. The states alleged that

AstraZeneca unlawfully marketed Seroquel for a number of off-label uses, including for use in pediatric and geriatric populations, specifically in nursing homes for Alzheimer's Disease and Dementia, as well as for anxiety, depression, sleep disorders, and post traumatic stress disorder. AstraZeneca promoted Seroquel for such uses, even though Seroquel was not, at the time it was marketed, approved for the treatment of these conditions and AstraZeneca had not established that Seroquel was safe and effective for these uses.

Atypical antipsychotics, including Seroquel, can produce dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications, an increased risk of mortality in elderly patients with dementia and other severe conditions.

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